

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 06275-0150003	Application No. 10/010,283
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Carl-Axel Bauer et al.	
		Filing Date November 13, 2001	Group Art Unit 1617

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	1	U.S. Examiner Jennifer M. Kim, Final Office Action in U.S. Serial No. 09/367,950, mailed March 17, 2010 (19 pages).
	2	Fish & Richardson Response to Office Action in U.S. Serial No. 10/665,240, mailed March 4, 2010, filed June 3, 2010 (23 pages).
	3	Barnes, "Chronic Obstructive Pulmonary Disease," Medical Progress, Vol. 343(4), pages 269-280 (2000).
	4	Bateman et al, "Overall asthma control: The relationship between current control and future risk," J. Allergy Clin. Immunol., Vol. 125(3), pages 600-608e6 (2010).
	5	Bousquet et al., "Budesonide/formoterol for maintenance and relief in uncontrolled asthma vs. high-dose salmeterol/fluticasone," Respiratory Medicine, Vol. 101, pages 2437-2446 (2007).
	6	BTS Guidelines for the Management of Chronic Obstructive Pulmonary Disease, Thorax, Vol. 52(a), pages S1-S28 (1997).
	7	Calverley et al., "Preventing mortality in COPD: The value of inhaled budesonide added to bronchodilators." Presentation at COPD5, Birmingham, UK, 28 June 2006, Abstract 35.
	8	Cates et al. "Combination formoterol and budesonide as maintenance and reliever therapy versus inhaled steroid maintenance for chronic asthma in adults and children (Review)," Published by Wiley and Sons, Ltd., 64 pages (2010).
	9	Chapman, "SMART isn't," J. Allergy Clin. Immunol., Vol. 125, pages 609-610 (2010).
	10	Dalby et al., "The bioavailability and airway clearance of the steroid component of budesonide/formoterol and salmeterol/fluticasone after inhaled administration in patients with COPD and healthy subjects: a randomized controlled trial," Respiratory Research, Vol. 10(104), pages 1-11 (2009).
	11	Definitions, Epidemiology, Pathophysiology, Diagnosis, and Staging, American Journal of Respiratory and Critical Care Medicine, Vol. 152, pages S78-S121 (1995).
	12	D'Urzo, "Inhaled Glucocorticosteroid and Long-Acting β_2 -Adrenoceptor Agonist Single-Inhaler Combination for Both Maintenance and Rescue Therapy," Treat Respir Med 5:385-391 (2006)
	13	Edwards et al., "Budesonide/formoterol for maintenance and reliever therapy of asthma: a meta analysis of randomised controlled trials," The International Journal of Clinical Practice, Vol. 64(5), pages 619-627 (2010).
	14	Jones et al., "St George's respiratory questionnaire (SGRQ) scores may help identify COPD patients at increased risk of death over 1 year." Presentation at COPD5, Birmingham, UK, 28 June 2006, Abstract 34.
	15	Kuna et al., "Effect of budesonide/formoterol maintenance and reliever therapy on asthma exacerbations," Int. J. Clin. Pract., Vol. 61(5), pages 725-736 (2007).
	16	Martin and Kraft, ed., <u>Combination Therapy for Asthma and Chronic Obstructive Pulmonary Disease</u> , Marcel Dekker, Inc., 2000, pages 274-293.
	17	Partridge et al., "Effect on lung function and morning activities of budesonide/formoterol versus salmeterol/fluticasone in patients with COPD," Therapeutic Advances in Respiratory Disease, Vol. 3(4), pages 147-157 (2009).
	18	Pavord et al., "Airway inflammation in patients with asthma with high-fixed or low-fixed plus as-needed budesonide/formoterol," J. Allergy Clin. Immunol., Vol. 123(5), pages 1083-1089.e7 (2009).
Examiner Signature		Date Considered
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	19	Product Information for "Foradil Dosis-aerosol," Netherlands authorization date 04 March 1992, Medicines Data Bank (downloaded from the Internet on 1/28/05), followed by a nine-page printout from the register of the Medicines Evaluation Board of the Netherlands regarding formoterol fumarate dihydrate, dated 15 July 2003, pages 1-9.
	20	Rabe et al., "Effect of budesonide in combination with formoterol for reliever therapy in asthma exacerbations: a randomised controlled, double-blind study," The Lancet, Vol. 368, pages 744-753 (2006).
	21	Rennard et al., "Efficacy and Tolerability of Budesonide/Formoterol in One Hydrofluoroalkane Pressurized Metered-Dose Inhaler in Patients with Chronic Obstructive Pulmonary Disease," Drugs, Vol. 69(5), pages 549-565 (2009).
	22	Scicchitano et al., "Efficacy and safety of budesonide/formoterol single inhaler therapy versus a higher dose of budesonide in moderate to severe asthma," Current Medical Research and Opinion, Vol. 20(9), pages 1403-1418 (2004).
	23	Siafakas et al., "Optimal assessment and management of chronic obstructive pulmonary disease (COPD)," European Respiratory Journal, Vol. 8, pages 1398-1420 (1995).
	24	Tashkin et al., "Efficacy and Safety of Budesonide and Formoterol in One Pressurized Metered-Dose Inhaler in Patients with Moderate to Very Severe Chronic Obstructive Pulmonary Disease," Drugs, Vol. 68(14); pages 1975-2000 (2008).
	25	Taylor, et al., "A new perspective on concepts of asthma severity and control," Eur. Respir. J. Vol. 32, pages 545-554 (2008).
	26	Urbano, "Review of the NAEPP 2007 Expert Panel Report (EPR-3) on Asthma Diagnosis and Treatment Guidelines," Journal of Managed Care Pharmacy, Vol. 14(1), pages 41-49 (2008).
	27	Wasserman, "What Is A Rescue Medicine And When Is It Used To Treat Asthma?," ABC News, 2 pages (2008).
	28	Venner Shipley LLP, Letter to the European Patent Office regarding opposition to EP Patent No. 1085877, filed by Generics (UK) Limited (April 20, 2010)
	29	Welte et al., "Efficacy and Tolerability of Budesonide/Formoterol Added to Tiotropium in Patients with Chronic Obstructive Pulmonary Disease," Am. J. Respir. Crit. Care Med., Vol. 180, pages 741-750 (2009).

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